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COMMITTEE ON APPROPRIATIONS
SUBCOMMITTEE ON HOMELAND SECURITY

REGARDING
BIOSHIELD AND BIOTERRORISM

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Chairman Gregg, Senator Byrd, and Members of the Committee, it is an honor for me to testify before you today regarding my views on the Project Bioshield Act of 2004 and whether we are meeting the biodefense needs of the United States.

I appear before you today as someone who has worked with industries helping to supply the United States with critical biodefense, chemical, radiological, and nuclear countermeasures since even before the attacks of 2001. During this time, I have worked with a number of large pharmaceutical companies, mid and small size biotechs, and companies that provide detection equipment and other ancillary services to help protect the nation from the threat of biological, chemical, nuclear, or radiological weapons. I also have had the opportunity to work with Congress and the Administration to help formulate policies to stimulate the creation of a thriving bio-defense industry in America. I and other members of our firm have provided testimony to both the House and Senate regarding the Project Bioshield Act of 2004 and we continue to work closely with your staff, Mr. Chairman, and the staff of other leaders in this area, including Senator Lieberman, Senator Kennedy, Senator Burr, and Senator Enzi, to ensure the best possible policies are in place to promote the deployment of the best possible countermeasures in this critical area.

During the last three years, I have been personally involved with a number of direct negotiations with the Department of Health and Human Services (HHS) for a number of critical biodefense countermeasures, as well as negotiations for contracts for critical vaccines for emerging infectious disease such as SARS, Avian influenza, and pandemic influenza. That said, it is my view, and I believe the view of many others in this industry, that HHS should be given additional tools to maximize participation of the entities that are best suited to provide critical countermeasures.

First among these additional tools must be expanded authority to address the issue of unmitigated liability associated with undertaking Bioshield contracts.

Liability Must be Addressed to Have a Successful Bio-Defense Industry

Industry concerns over the massive cost of product liability lawsuits are preventing critical countermeasures from being developed for the Strategic National Stockpile (SNS). The liability concerns of a company engaged in day-to-day drug development are clearly different from the liability concerns of a company participating in Project Bioshield. Manufacturers of countermeasures produced under Project Bioshield risk exposure to devastating product liability lawsuits to a far greater degree than typical drug companies. Safety and efficacy data must be derived, for the most part, from animal trials since healthy humans cannot be exposed to toxic agents during testing. Thus, these critical countermeasures must

be developed and are likely to be deployed without the full battery of testing typical of other drugs. Without liability protections, responsible companies will remain on the sidelines for fear of risking corporate assets to defend lawsuits brought as a result of producing a countermeasure that generally has a much lower profit margin than a typical pharmaceutical product.

Even as the Federal government has begun to purchase Bioshield countermeasures, it has no current way to resolve issues of liability with any degree of certainty. As a result, needed countermeasures are not being developed and deployed, thereby exposing the economy, and the nation as a whole, to far greater potential liability due to the lack of available effective countermeasures in the event of attack. Either way, the Federal government is likely to the bear both the human and financial cost of such an attack as it did on September 11th. By failing to account for these costs before an attack, countermeasures will not be developed and the nation will be more exposed to attack.

Senate Bill 3 attempts to address these liability concerns for not only terrorism, but also countermeasures developed and deployed to protect the United States against naturally occurring epidemics such as SARS and pandemics such as Avian influenza. These epidemics and pandemics have the potential to be even more costly in terms of lives and dollars than even the worst terrorist attack. By addressing the issue of liability before an event occurs, we are not only assuring that needed countermeasures are developed, but also, being fiscally responsible by mitigating at the least economic cost of such a tragedy and reducing the cost of needless litigation.

While the similarities between the public health threats of bio-defense and infectuous disease are obvious, I would strongly urge Congress to consider - and act upon - liability protections that are necessary to bring a pandemic influenza vaccine to market as quickly as possible. The dangers of a pandemic are real and immediate. Should the nation face a pandemic similar to the one it faced in 1918 and 1919 with the Spanish flu, millions of American are certain to die. While I do believe Senate Bill 3 provides adequate protections to stimulate the creation of a bio-defense industry, it is inadequate to protect providers of pandemic vaccine given that the response to such an event would be to quickly vaccinate nearly 300 million Americans. Thus, the response to a pandemic is similar to -- and perhaps, far broader than -- the response to a potential outbreak of smallpox. For this reason, the liability protections provided for a pandemic influenza vaccine provider must be at least as strong as those protections given to providers of smallpox vaccine under the Homeland Security Act of 2002.

Under the Homeland Security Act of 2002, manufactures, suppliers and administrators of smallpox vaccine are immune from any and all liability resulting from the administration of the vaccine during a declared emergency. These

protections provide the certainty necessary to ensure the nation has an adequate supply of smallpox vaccine in the event of an attack. While there are several improvements that should be made to this legislation to ensure health care workers are properly compensated, these same types of protections must be extended to providers of pandemic influenza vaccine.

Available Liability Mitigation Tools are Inadequate

Under current law, there are currently only two legal authorities that allow the Federal government to mitigate the liability concerns for providers of countermeasures other than smallpox vaccine - through Federal indemnification under Public Law 85-804 and through designation/certification under the SAFETY Act. Both measures are inadequate to address the practical realities of potential litigation facing the providers of countermeasures and the fiscal realities facing the Federal government

Public Law (P.L.) 85-804 grants the President an extremely broad authority to allow a Federal government contractor to obtain financial or other forms of relief under certain circumstances, even when the government may have no express legal obligation to grant such relief, or when there are express prohibitions against such relief contained in other statutes, regulations, or common law. Under this authority, the heads of designated departments or agencies have the discretionary power to provide contractors with government indemnity when they are engaged in "unusually hazardous" activities and when it is in the interest of the national defense to provide such indemnity.

Indemnification under P.L. 85-804 relies upon the American tort system and places the Federal government in the position of an insurer - where payments are made only after all claims have been adjudicated in the court system and judgments have been rendered. This rather lengthy process does not result in compensation to victims being paid in a timely manner nor does it place any effective limits on the Federal government's potential payments to victims when it acts in this capacity.

Although this authority has been invoked by the Department of Health and Human Services (which was first granted the authority in October 2001 following the anthrax attacks) in agreements involving the donation of smallpox vaccine by Wyeth and Aventis Pasteur to the Federal government in 2001, HHS will only address the issue of indemnification prior to the award of a contract for a countermeasure. As a result, potential providers of countermeasures must expend scarce resources to prepare and submit a proposal that may result in a contract that cannot be accepted due to the lack of liability protections should HHS ultimately refuse to provide indemnification. More often, companies simply refuse to bid at all due to the lack of certainty on the issue of liability. This has resulted in the largest, and far more experienced, drug companies with the necessary expertise to address this threat being left on the sidelines.

Moreover, HHS and OMB have taken the position that indemnification under Public Law 85-804 cannot be granted to protect suppliers of pandemic influenza vaccine since there is not an immediate connection to national security. This extremely narrow view of what constitutes "national security" ignores the implications that our troops stationed in Southwest Asia (which is currently facing a potential Avian Flu epidemic), it also ignores the national security implications of having millions of America perish in a pandemic. Thus, Congress must address this issue immediately to ensure the nation is fully prepared.

Congress did attempt to address the issue of liability associated with anti-terrorism goods and services with the passage of the SAFETY Act in November 2002. The SAFETY Act does, in fact, provide significant protections to providers of countermeasures that receive certification under the Act. However, to date, no such certifications have been granted for bio-defense countermeasures. In addition, there are specific limitations upon the effectiveness of the SAFETY Act for providers of countermeasures under Project Bioshield.

Section 865(1) of the SAFETY Act notes that qualified anti-terrorism technologies may include technologies deployed for the purpose of "limiting the harm such acts [of terrorism] might otherwise cause." The "harm" that may be caused by an act of terrorism clearly goes beyond the immediate effects of the Act itself. An act of terrorism such as the attacks of September 11th or the October 2001 anthrax attacks trigger a number of immediate remedial and emergency responses to limit the resulting harm and deter follow-on attacks.

While the SAFETY Act can provide signification protections to a company, its application in the context of countermeasures is extremely limited. Most significantly, the potential liability of a provider of anti-terrorist technologies that may allegedly cause injury PRIOR to a terrorist attack, such as a vaccine, are not currently addressed by the SAFETY Act. This limitation of the SAFETY Act leaves providers of anti-terrorism vaccines without any adequate projections aside from the possibility of Federal indemnification.

Moreover, SAFETY Act certification is most inadequate to provide the type of protections required for large companies to enter the market for countermeasures. Holders of SAFETY Act certification are still faced with the possibility of hundreds of lawsuits brought against them throughout the country, albeit in Federal court. Since the SAFETY Act protections must be asserted as an affirmative defense to any lawsuit, the unpredictability of the American judicial system still places providers of countermeasures with a large degree of uncertainty regarding potential liability. This uncertainty, coupled with the "gap" in the SAFETY Act for vaccine providers and the cumbersome nature of the application process to receive SAFETY Act certification makes it an inadequate protection for providers of countermeasures under Project Bioshield.

For all of these reasons, Congress should equip HHS with the adequate tools to address liability concerns that are inhibiting the development and deployment of critical countermeasures as soon as possible. More over, it is in the best interests of the United States that Congress act immediately to extend the same types of protections afforded to providers of smallpox vaccine to providers of pandemic influenza vaccine to ensure an adequate response to the certain public health crisis an influenza pandemic will cause the United States unless we are adequately prepared.

Additional Regulatory Relief for Providers of Countermeasures is Needed

The Project Bioshield Act of 2004 makes great strides to reduce many of the regulatory burdens that are obstacles to allowing companies that do not traditionally sell the Federal government to participate in the development of needed countermeasures. Based upon the experience of industry during the first procurements conducted Bioshield, more can be done to reduce the amount unnecessarily burdensome regulations. To date, industry reaction to Bioshield has been muted, partly because of initial implementation challenges and partly because the scope and incentives of Bioshield are too limited to attract serious attention from investors, including venture capitalists, institutional investors, or manufacturers that are needed to grow the biodefense industry.

It is important to examine the first actions HHS has taken under the Project Bioshield to understand the challenges in implementing the statute, as well as the need for additional procurement reforms.

On October 26, 2004, HHS received the first proposals to provide therapeutic products for treatment of inhalational anthrax disease in response to Solicitation No. 2004-N-01385 (the "Anthrax Therapeutics Solicitation") under what was the first, true, Project Bioshield procurement. Just over two weeks later, on November 4, 2004, VaxGen, Inc. ("VaxGen") received an award of a large contract to produce an experimental recombinant protective antigen anthrax vaccine ("rPA").

While this award to VaxGen was the first countermeasure contract funded from Bioshield's Special Reserve Fund, this was not a true Bioshield procurement. In fact, all of the research and development for this countermeasure was funded at the taxpayer's expense through the National Institute for Allergy and Infectious Disease under two earlier awards totaling over $200 million. Unlike the goals of Bioshield to create a market to encourage private investment, the first award funded by Bioshield was a very typical, multi-stage, Federal procurement fully funded at the taxpayer's expense, without utilizing any of the unique authorities Congress provided to HHS under Project Bioshield.

The first Bioshield procurement for Anthrax therapeutics solicitation is for the acquisition and maintenance within the SNS of therapeutic products to treat US civilians who have inhalational anthrax disease. The Anthrax therapeutics solicitation contemplates that the awarded contract(s) will be for 10 grams of an investigational new drug ("IND") for use in testing. The actual manufacture of anthrax therapeutic product is an optional contract line item, which the government may decide to exercise within 12 months from the date of contract award and after the government reviews and approves the test sample. However, while this procurement could have utilized the streamlined procurement provisions provided under Project Bioshield, the solicitation includes numerous provisions of the Federal Acquisition Regulation ("FAR") and other detailed requirements for bidders, including detailed rules governing the methods of preparing pricing for the proposal.

This initial Bioshield solicitation was curious in three ways. First, the way the solicitation structures the options in the contract fall short of the Congressional intent of the Act to provide for a commitment to recommend funding for production for the SNS as contemplated by Project Bioshield. Contrary to the intent of the Act, HHS has not committed to recommend exercise of the options for production quantities of the countermeasure upon successful development of the countermeasure. Such a commitment would help to advance the Act's purpose of promoting the development of a biodefense industry by informing the markets that there is some certainty that there will be a government market for the product. Second, as noted above, the solicitation failed to use the simplified acquisition authorities that Bioshield makes available to the government, which would have permitted far fewer bidding requirements. Third, the solicitation makes IND status an absolute criteria for award of the contract. This has been criticized as unduly - restricting the ability of companies with promising technologies that have not yet reached IND FDP status from competing.

Unlike the Anthrax therapeutics solicitation, the VaxGen solicitation did not suffer from a lack of commitment to production quantities. The scope of work for the rPA contract requires VaxGen to manufacture and deliver to the SNS 75 million doses of experimental (and non-FDA approved) rPA vaccine in pre-filled syringes along with safety needles (with a minimum of 25 million doses delivered within two years of contract award). The contract also requires a variety of ancillary commitments by VaxGen related to testing and licensing.

The VaxGen contract is valued at $877.5 million, representing approximately 15% of the amounts appropriated for Project Bioshield for the next 10 years. The contract provides for payments to VaxGen of $754 million in advance of the following milestones: 1) approval of a Biologics License Application ("BLA") for general use prophylaxis, 2) approval of a BLA for post exposure prophylaxis; and 3) demonstration of 18 months of real time stability in pre-filled syringes. When and if

these milestones are accomplished, VaxGen will receive specified per dose price supplements.

There are three main criticisms of the VaxGen contract. First, it appears that, as with the Anthrax therapeutics solicitation, HHS elected not to use simplified acquisition procedures in awarding the contract. Second, despite the availability of an FDA licensed competing vaccine technology, HHS restricted the competition for the contract to firms that produced rPA-based vaccines, which have not been advanced beyond early testing in the regulatory approval process. This has made the government and the nation's security against anthrax attacks highly dependent on an early stage, unproven technology. Third, the government awarded the contract to a single vendor, thereby making the nation's security against such attacks dependent on this single vendor.

Proposed Implementation Improvements

HHS can take several steps to implement Bioshield to increase industry participation. To fully realize the legislative intent of the law, HHS should enact regulations required under the Project Bioshield Act that take into account the following issues:

- Specify that Project Bioshield Act procurements include only those FAR clauses specifically required by FAR Part 13, Simplified Acquisition Procedures;

- Fully describe how HHS and DHS will make a determination of a material threat and the other determinations required by the Project Bioshield Act;

- Provide for determinations of the order in which the government plans to procure countermeasures;

- Require HHS to specify a firm number of doses or courses of treatment in the call for countermeasures stage;

- Provide for industry participation in market surveys undertaken during the assessment of the availability and appropriateness of countermeasures stage;

- Provide critical suppliers of needed medical countermeasures annual "warm base" funding to ensure that the US Government will have continued access to those products following any procurement contract;

- Provide that multiple products manufactured by multiple suppliers using multiple technologies be procured where practicable to avoid undue dependence on any single supplier or single technology;

- Provide that countermeasures that are already licensed by the Food and Drug Administration should where possible be purchased under Project Bioshield; and

- Provide for the appropriate use of HHS' "Other Transaction" Authority in procurements under Sections 2 and 3 of the Project Bioshield Act, in accordance with the authority provided to HHS by Title XVI of the Fiscal Year 2004 Defense Authorization Act.

Also, as required by Section 319F-2(c)(4)(C)(ii) of the Public Health Act, HHS should, in a call for bio-terrorism countermeasures, provide industry with an estimate of the quantities of a countermeasure (in the form of number of doses or number of effective courses of treatment) that HHS intends to procure upon development of a countermeasure that meets the statutory criteria. Providing industry with wide ranges of potential requirements for a countermeasure, as HHS did in the Anthrax therapeutics solicitation, does not serve the statutory purpose of promoting the development of a biodefense industry because it introduces additional uncertainty about the size of the government market for the countermeasure.

HHS and the Department of Homeland Security ("DHS") should provide industry with information concerning the implementation of the Project Bioshield Act. For example, HHS and DHS should provide industry and the public with a status report concerning the governmental processes required by Section 319F-2(c)(2)-(6) of the Public Health Act. HHS should also publish the report on the adequacy of biocontainment facilities required by Sec. 5(c) of the Project Bioshield Act. This report was due in January, and yet, has not been completed or provided to industry.

Perhaps most important, DHS should inform industry of the progress and priority of the required threat assessments so that companies can make proper business decisions in their planning process. Project Bioshield requires that the DHS, in conjunction with the HHS, conduct a threat assessment to "assess current and emerging threats of chemical, biological radiological, and nuclear agents; and determine which of such agents present a material threat against the United States population sufficient to affect national security" and for which a countermeasure is needed. As implemented, this threat assessment must be conducted prior to any decision to purchase a needed countermeasure under the Project Bioshield.

It is my understanding that, to date, no such assessment has been conducted to determine the threat of cyanide to the American people. Aside from cyanide's historical use as a battlefield weapon in World War I, this country has already suffered from terrorist attacks and plots using cyanide: in the 1980s, with the tampering of Tylenol; in 2003, with the discovery of a cyanide bomb in the possession of a white supremacist in Texas that held enough cyanide to fatally gas everyone in a 30,000 sq ft facility; and, in early 2004, with the discovery by U.S. troops in Baghdad of a 7-pound block of cyanide salt. Moreover, soon after our successful liberation of Afghanistan in 2002, our forces discovered Al Qaeda training videos using cyanide to poison dogs and other animals.

I note that in the legislative history of the Project Bioshield, a potential treatment for cyanide poisoning, hydroxocobalamin is specifically identified in the reports filed by the House Committees on Government Reform and Energy and Commerce. Thus, providers of this countermeasure are "on hold" pending completion of this threat assessment. Providing this information to industry will aid industrial base planning efforts and thereby promote the Project Bioshield Act's objective of fostering the development of a biodefense industry.

In addition to the specific recommendations above that should be taken into account during regulatory process and in order to carry forth the initiative's legislative intent, we have several policy suggestions that should be considered in implementing Project Bioshield: HHS should keep in mind that the government's use of multiple countermeasure suppliers and technologies would be in the overall interests of public health and homeland security. As evidenced by the recent influenza vaccine shortage, having a diverse "portfolio" of countermeasures in the strategic national stockpile will facilitate flexibility in responding to bioterrorism threats and attacks.

First and foremost, HHS should make clear that the statute does not require contractors to comply with burdensome government procurement requirements, including the requirement for certified cost and pricing data, in order to stimulate the maximum interest possible by commercial companies. Similarly, HHS should avoid the use of cost-type contracts or contract line items (thus, eliminating the need for a proposed contractor to adopt non-GAAP accounting practices) wherever possible.

HHS should structure Bioshield contracts to avoid a "staged" procurement approach such as that announced in the recent Anthrax therapeutic request for proposal, wherever possible. While we recognize the need for staged procurements under certain circumstances, using this method where HHS has conducted proper market research will avoid unnecessary delays and unpredictable results, thereby stimulating far greater private sector interest.

Maximizing the use of these authorities, as well as enactment of the additional streamlined authorities identified above, will go a long way to ensuring the greatest possible participation in Bioshield. Moreover, as we have already seen in how slow the contracting process has been to date with Bioshield, failure to act on these procurement reforms will cost the nation something that no amount of money or any act of Congress can ever make up for - time.

I very much appreciate the opportunity to offer testimony on this very important public health and anti-terrorism issue. Achieving the objectives of the Project Bioshield Act of 2004 and Senate Bill 3 are of the utmost importance to ensuring homeland and national security. Again, I applaud your efforts, and the efforts of President Bush and his Administration, and look forward to continuing our work with Congress and the Administration in this critical area.

I am happy to respond to any questions you may have.